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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,862	04/02/2002	David A. Jones	1321.2.34.1	1434

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EXAMINER	
RAWLINGS, STEPHEN L	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,862	JONES ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *18 and 19* is/are withdrawn from consideration.

5)☒ Claim(s) *9* is/are allowed.

6)☒ Claim(s) *1-8 and 10-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 April 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5/24/02
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of the invention of Group I, claims 1-17, in the reply filed June 11, 2004 is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-19 are pending in the application. Claims 18 and 19 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

3. Claims 1-17, drawn to a nucleic acid molecule, a vector comprising said nucleic acid molecule, and a host cell comprising said vector, are currently under prosecution.

Information Disclosure Statement

4. The information disclosure filed May 8, 2002 has been considered. An initialed copy is enclosed.

Specification

5. The specification is objected to because the use of improperly demarcated trademarks has been noted in this application. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. See MPEP § 608.01(v).

Examples of improperly demarcated trademarks include: ABI PRISM (page 14, line 5), Phosphorimager™ (page 14, line 15), and Cytofluor™ (page 16, line 31).

Appropriate correction is required. Each letter of a trademark should be capitalized or otherwise the trademark should be demarcated with the appropriate symbol indicating its proprietary nature (e.g., ™, ®), and accompanied by generic

terminology. Applicants may identify trademarks using the "Trademark" search engine under "USPTO Search Collections" on the Internet at http://www.uspto.gov/web/menu/search.html.

6. The specification is objected to for the following informalities: At page 10 in line 11 there is no typed space between "examined" and "(Figure 3A)", where there should be a typed space. Appropriate correction is required.

Claim Objections

7. Claims 6-8, 12, and 14-17 are objected to because of the following informalities:

(a) Claims 6-8 and 15-17 are objected to because claims 6 and 15 recite, "the vector acid" of claims 2 and 11, respectively. Likely the result of an inadvertent typographical error, it appears claims 6 and 15 should recite, "the vector" of claims 2 and 11, respectively, since claims 2 and 11 are drawn to a recombinant vector. Appropriate correction is required.

(b) There is clearly a typed space between "of" and "claim 11" in claim 13, so it appears that there is no typed space between "of" and "claim 11" in claims 12 and 14. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 10-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In part, claims 10-17 are directed to a nucleic acid molecule comprising a nucleotide sequence complementary to the nucleotide sequence of SEQ ID NO: 1. Notably, the claimed nucleic acid molecule need not comprise a polynucleotide sequence that is the full complement of the nucleotide sequence of SEQ ID NO: 1. Moreover, the claimed nucleic acid molecule need not comprise a polynucleotide sequence containing the complement of the full-length open reading frame, which the specification discloses encodes the amino acid sequence of SEQ ID NO: 2, or for that matter the full-length open reading frame, or the full complement thereof, encoding any other protein.

Although the claimed nucleic acid molecule must have a polynucleotide sequence that is complementary to the nucleotide sequence set forth as SEQ ID NO: 1, this common structural feature of the nucleic acid molecules encompassed by the claim does not relate to any particularly identifying structural feature of the proteins encoded thereby, nor does it relate any particularly identifying functional feature of either the nucleic acid molecules or their translation products.

Given the broadest reasonable interpretation of the claim, the claimed nucleic acid molecule can merely have a nucleotide sequence that is complementary to a portion of the nucleotide sequence of SEQ ID NO: 1. The claimed nucleic acid molecule can be different or unrelated to the nucleic acid molecule encoding the polypeptide of SEQ ID NO: 2, provided it comprises a polynucleotide sequence that comprises at least a portion complementary to the nucleotide sequence of SEQ ID NO: 1. Accordingly, the claims are directed to a genus of nucleic acid molecules, which the members can vary markedly in both structure and function.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, ``Written Description" Requirement (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). The

Guidelines further state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. Because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant had possession of the claimed invention at the time the application was filed.

The specification provides an adequate written description of nucleic acid molecules that comprise or consist of SEQ ID NO: 1, nucleic acid molecules that comprise or consist of the *full* complement of the nucleotide sequence of SEQ ID NO: 1 or the *full* complement of a nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 2, nucleic acid molecules that *consist* of a polynucleotide sequence of SEQ ID NO: 1 (e.g., a nucleic acid molecule consisting of a fragment of SEQ ID NO: 1), and nucleic acid molecules that *consist* of a polynucleotide sequence that is complementary to the nucleotide sequence of SEQ ID NO: 1 (e.g., a nucleic acid molecule consisting of the full complement of a fragment of SEQ ID NO: 1).

However, the description of these few members of the claimed genus of nucleic acid molecules is not sufficient to meet the requirements of 35 USC § 112, first paragraph, since the genus embraces widely variant members and an adequate description of such cannot be achieved by describing members, which are not representative of the genus. As disclosed and claimed, the genus of nucleic acid molecules does not comprise members having a common, particularly identifying

structural feature that correlates with a common functional feature shared by at least a substantial number of its members. As such, absent any of the factual evidence of an actual reduction to practice discussed above, the skilled artisan could not immediately envision, recognize, or distinguish at least a substantial number of the members of the claimed genus said at least substantial number. Accordingly, the specification would not reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed.

Amending claim 10 to read, for example, "[...] comprising the nucleotide sequence of SEQ ID NO: 1 or the full complement thereof" can remedy this issue.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Boehringer Mannheim Biochemicals, 1994 Catalog (No. 1034 731/1006 924), page 93.

In part, claim 10 is drawn to an isolated and purified nucleic acid comprising a nucleotide sequence complementary to the nucleotide sequence of SEQ ID NO: 1, including but not limited to a nucleic acid molecule comprising the full complement of the nucleotide sequence of SEQ ID NO: 1.

The Boehringer Mannheim catalog teaches a kit comprising a collection of random primers. The collection comprises a multitude of isolated and purified nucleic acid molecules (i.e., primers), each of which consists of 6 nucleotide residues. The

collection comprises nucleic acid molecules having every possible 6-nucleotide sequence of the four different nucleotide residues (i.e., A, C, T, and G) of which DNA is comprised. Therefore, the kit comprises an isolated nucleic acid molecule consisting of a polynucleotide sequence that is, itself, fully complementary to a nucleotide sequence of a nucleic acid molecule having the polynucleotide sequence of SEQ ID NO: 1. Because claim 10 is drawn to an isolated and purified nucleic acid comprising a nucleotide sequence complementary to the nucleotide sequence of SEQ ID NO: 1, such as a random primer contained in the kit, the disclosure of the kit and its contents by the prior art is anticipatory of the presently claimed invention.

12. Claims 1-8 and 10-17 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,440,694 B1.

For clarity of record, herein, claims 6 and 15 have been drawn to a host cell comprising the "vector" of claims 2 and 11, respectively, as opposed to a "vector acid", which appears to be a typographical error, since the term "vector acid" does not appear in claims 2 or 11. Claim 10 is drawn to an isolated and purified nucleic acid comprising a nucleotide sequence complementary to the nucleotide sequence of SEQ ID NO: 1, including but not limited to a nucleic acid molecule comprising the full complement of the nucleotide sequence of SEQ ID NO: 1.

US Patent No. 6,440,694 B1 ('694) teaches a nucleic acid molecule comprising the polynucleotide sequence set forth therein as SEQ ID NO: 3; see the entire document (e.g., Figure 4). '694 teaches the polynucleotide sequence of the nucleic acid molecule encodes a polypeptide having the amino acid sequence set forth therein as SEQ ID NO: 4; see, e.g., Figure 4. SEQ ID NO: 4 of the prior art and SEQ ID NO: 2 of the instant application are identical. Accordingly, '694 teaches a nucleic acid molecule comprising a nucleotide sequence encoding the amino acid sequence set forth as SEQ ID NO: 2 in the instant application. SEQ ID NO: 3 of the prior art is not identical to, nor does it comprise the polynucleotide sequence set forth as SEQ ID NO: 1 in the instant application; however, claim 10 does not limit the claimed nucleic acid molecule to a nucleic acid molecule comprising the *full* complement of the nucleotide sequence of

SEQ ID NO: 1 and the complement of SEQ ID NO: 3 of the prior art comprises a nucleotide sequence that is complementary to the nucleotide sequence of SEQ ID NO: 1. In fact, the complement of the polynucleotide sequence of SEQ ID NO: 3 of the prior art comprises a nucleotide sequence that is fully complementary to the entire open-reading frame of the instant nucleotide sequence of SEQ ID NO: 1, which encodes the instant amino acid sequence of SEQ ID NO: 2, i.e., it comprises a nucleotide sequence fully complementary to the nucleotide sequence of SEQ ID NO: 1 from the nucleotide at position 61 to the nucleotide at position 801 of the SEQ ID NO: 1. In addition, '694 teaches the polynucleotide sequence of the disclosed nucleic acid molecule or its complement, or a fragment thereof, can be incorporated into an expression vector (i.e., a plasmid), such that the polynucleotide sequence is operably linked to a heterologous promoter; see, e.g., column 3 (lines 26-29 and 37-41); column 10 (line 66) through column 11 (line 20); and column 12 (lines 7-15). '694 teaches prokaryotic and eukaryotic host cells comprising such vectors; see, e.g., column 11 (lines 63 and 64).

13. Claims 1-8 and 10-17 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application No. 20030044937 A1.

US Patent Application No. 20030044937 A1 (Bienkowski et al.) teaches a nucleic acid molecule comprising the polynucleotide sequence set forth therein as SEQ ID NO: 3; see the entire document (e.g., Figure 4). Bienkowski et al. teaches the polynucleotide sequence of the nucleic acid molecule encodes a polypeptide having the amino acid sequence set forth therein as SEQ ID NO: 4; see, e.g., Figure 4. SEQ ID NO: 4 of the prior art and SEQ ID NO: 2 of the instant application are identical. Accordingly, Bienkowski et al. teaches a nucleic acid molecule comprising a nucleotide sequence encoding the amino acid sequence set forth as SEQ ID NO: 2 in the instant application. SEQ ID NO: 3 of the prior art is not identical to the polynucleotide sequence set forth as SEQ ID NO: 1 in the instant application; however, claim 10 does not limit the claimed nucleic acid molecule to a nucleic acid molecule comprising the *full* complement of the nucleotide sequence of SEQ ID NO: 1 and the complement of SEQ ID NO: 3 of the prior art comprises a nucleotide sequence that is complementary to the

nucleotide sequence of SEQ ID NO: 1. In fact, the complement of the polynucleotide sequence of SEQ ID NO: 3 of the prior art comprises a nucleotide sequence that is fully complementary to the entire open-reading frame of the instant nucleotide sequence of SEQ ID NO: 1, which encodes the instant amino acid sequence of SEQ ID NO: 2, i.e., it comprises a nucleotide sequence fully complementary to the nucleotide sequence of SEQ ID NO: 1 from the nucleotide at position 61 to the nucleotide at position 801 of the SEQ ID NO: 1. In addition, Bienkowski et al. teaches the polynucleotide sequence of the disclosed nucleic acid molecule or its complement, or a fragment thereof, can be incorporated into an expression vector (i.e., a plasmid), such that the polynucleotide sequence is operably linked to a heterologous promoter; see, e.g., page 2 (paragraphs [0022] and [0023]); page 6 (paragraph [0109]); and page 7 (paragraph [0114]). Bienkowski et al. teaches prokaryotic and eukaryotic host cells comprising such vectors; see, e.g., page 7 (paragraphs [0114] – [0117]).

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-4, 6-8, 10-13, and 15-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,440,694 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application and the claims of the patent are drawn to nearly the same invention.

Claims 1-3 and 12-19 of the patent are drawn to a nucleic acid molecule comprising a polynucleotide sequence having a sequence encoding a polypeptide having the complete amino acid sequence of SEQ ID NO: 4. Claim 1 of the instant application is similarly drawn to such a nucleic acid molecule, since SEQ ID NO: 4, as disclosed by the patent, is identical to the amino acid sequence of SEQ ID NO: 2 encoded by the claimed nucleic acid molecule of the instant application.

Claim 10 of the instant application is drawn to an isolated and purified nucleic acid comprising a nucleotide sequence complementary to the nucleotide sequence of SEQ ID NO: 1, including but not limited to a nucleic acid molecule comprising the full complement of the nucleotide sequence of SEQ ID NO: 1. Because claim 2, for example, of the patent is drawn to a nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO: 3, which comprises a nucleotide sequence complementary to the nucleotide sequence of SEQ ID NO: 1, as disclosed by the instant application, although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 4 and 5 of the patent are drawn to a vector comprising the nucleic acid molecule of claim 1 operably linked to a promoter for expression of a protein encoded by the polynucleotide sequence of the nucleic acid molecule. Although claims 2-4 and 11-14 of the instant application are drawn to a similar vector, claims 3 and 12 are specifically drawn to the vector of claims 2 and 11, respectively, that is *a plasmid* and claims 4 and 13 are specifically drawn to the vector of claims 2 and 11, respectively, that is *a eukaryotic or prokaryotic expression vector.* Looking to the patent specification for a definition of the term "vector", as recited in claims 4 and 5 of the patent, it is determinable that within the scope of the meaning of the term is "plasmid", as recited in

claims 3 and 12 of the instant application; see, e.g., column 12, lines 11-15, and column 22, lines 14-16. Because claim 5 of the patent is drawn to a vector for expression of a protein and claim 8 is drawn to a host cell comprising such a vector that is eukaryotic, although the subject matter of conflicting claims 4 and 13 of the instant application and claims 4 and 5 of the patent are not identical, the claims are not patentably distinct from each other, as the differences would be obvious to one ordinarily skilled in the art.

Claims 6-10 of the patent are drawn to a host cell comprising the vector of claim 4; claims 6-8 and 15-17 of the instant application are drawn to similar subject matter. Claims 8-10 of the patent are specifically drawn to a host cell that is eukaryotic, as are claims 7 and 16 of the instant application. However, claims 8 and 17 of the instant application are specifically drawn to a host cell that is *prokaryotic*. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 7 of the patent is generically drawn to a host cell and claim 8 of the patent is drawn to the host cell of claim 7 that is eukaryotic. A host cell is either prokaryotic or eukaryotic. Accordingly, the differences between the conflicting claims would be obvious to one ordinarily skilled in the art.

16. Claims 5 and 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4 and 5 of U.S. Patent No. 6,440,694 B1 in view of Hasnain et al. (*Gene*. 1997 Apr 29; **190** (1): 113-118).

While claims 4 and 5 of the patent are drawn to a vector comprising a promoter operably linked to the nucleic acid molecule comprising the polynucleotide sequence encoding the protein of SEQ ID NO: 4 (i.e., SEQ ID NO: 2, as set forth in the instant application) and claims 5 and 14 of the instant application are drawn to similar subject matter, claims 5 and 14 are specifically drawn to a vector in which the promoter is a *heterologous* promoter.

Available on the Internet at http://biotech.icmb.utexas.edu/search/dict-search.html, the Biotech Life Science Dictionary defines the term "heterologous" as

"[d]erived from a separate genetic source or species" (© Copyright 1995-1998 Biotech Resources and Indiana University).

Hasnain et al. reviews the baculovirus expression vector system that has emerged as the system of choice for the expression of a number of nucleic acid molecules; see entire document, e.g., the abstract. Hasnain et al. describes expression vectors, which comprise the baculovirus very late, hyperactive polyhedrin and p10 promoters, which can be operably linked to the polynucleotide sequences encoding proteins for expression in the system; see, e.g., the abstract. As the polynucleotide sequences encoding such proteins can be of prokaryotic origin, for example, the promoters to which the polynucleotides sequences are operably linked for expression in the system are "heterologous", i.e., derived from a separate genetic source or species, namely baculovirus; see, e.g., the abstract.

Accordingly, although the conflicting claims are not identical, they are not patentably distinct from each other, since the differences would have been obvious to one ordinarily skilled in the art at the time of the invention, given the teaching of Hasnain et al.

17. Claims 1-4, 6-8, 10-13, and 15-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 10/174,654. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application and the claims of the copending application are drawn to nearly the same invention.

Claims 1-4 of the copending application are drawn to a nucleic acid molecule comprising a polynucleotide sequence having a sequence encoding a polypeptide having the complete amino acid sequence of SEQ ID NO: 4. Claim 1 of the instant application is similarly drawn to such a nucleic acid molecule, since SEQ ID NO: 4, as disclosed by the copending application, is identical to the amino acid sequence of SEQ ID NO: 2 encoded by the claimed nucleic acid molecule of the instant application.

Claim 10 of the instant application is drawn to an isolated and purified nucleic acid comprising a nucleotide sequence complementary to the nucleotide sequence of SEQ ID NO: 1, including but not limited to a nucleic acid molecule comprising the full complement of the nucleotide sequence of SEQ ID NO: 1. Because claim 2, for example, of the copending application is drawn to a nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO: 3, which comprises a nucleotide sequence complementary to the nucleotide sequence of SEQ ID NO: 1, as disclosed by the instant application, although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 5 and 6 of the copending application are drawn to a vector comprising the nucleic acid molecule of claim 1 operably linked to a promoter for expression of a protein encoded by the polynucleotide sequence of the nucleic acid molecule. Although claims 2-4 and 11-14 of the instant application are drawn to a similar vector, claims 3 and 12 are specifically drawn to the vector of claims 2 and 11, respectively, that is *a plasmid* and claims 4 and 13 are specifically drawn to the vector of claims 2 and 11, respectively, that is *a eukaryotic or prokaryotic expression vector*. Looking to the specification of the copending application for a definition of the term "vector", as recited in claims 5 and 6 of the copending application, it is determinable that within the scope of the meaning of the term is "plasmid", as recited in claims 3 and 12 of the instant application; see, e.g., page 7, paragraph [0114], and pages 12 and 13, paragraph [0213]. Because claim 6 of the copending application is drawn to a vector for expression of a protein and claim 9 is drawn to a host cell comprising such a vector that is eukaryotic, although the subject matter of conflicting claims 4 and 13 of the instant application and claims 5 and 6 of the copending application are not identical, the claims are not patentably distinct from each other, as the differences would be obvious to one ordinarily skilled in the art.

Claims 7-12 of the copending application are drawn to, or directed to a host cell comprising the vector of claims 5 or 7; claims 6-8 and 15-17 of the instant application are drawn to similar subject matter. Claims 9-11 of the copending application are specifically drawn to a host cell that is eukaryotic, as are claims 7 and 16 of the instant

application. However, claims 8 and 17 of the instant application are specifically drawn to a host cell that is *prokaryotic*. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 7 and 8 of the copending application are generically drawn to a host cell and claim 9 of the copending application is drawn to the host cell of claim 8 that is eukaryotic. A host cell is either prokaryotic or eukaryotic. Accordingly, the differences between the conflicting claims would be obvious to one ordinarily skilled in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claims 5 and 14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5 and 6 of copending Application No. 10/174,654 in view of Hasnain et al. (*Gene*. 1997 Apr 29; **190** (1): 113-118).

While claims 5 and 6 of the copending application are drawn to a vector comprising a promoter operably linked to the nucleic acid molecule comprising the polynucleotide sequence encoding the protein of SEQ ID NO: 4 (i.e., SEQ ID NO: 2, as set forth in the instant application) and claims 5 and 14 of the instant application are drawn to similar subject matter, claims 5 and 14 are specifically drawn to a vector in which the promoter is a *heterologous* promoter.

Available on the Internet at http://biotech.icmb.utexas.edu/search/dict-search.html, the Biotech Life Science Dictionary defines the term "heterologous" as "[d]erived from a separate genetic source or species" (© Copyright 1995-1998 Biotech Resources and Indiana University).

Hasnain et al. teaches that which is set forth above.

Accordingly, although the conflicting claims are not identical, they are not patentably distinct from each other, since the differences would have been obvious to one ordinarily skilled in the art at the time of the invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

19. Because a nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO: 1 is free of the prior art, and since there is no factual evidence that such a nucleic acid molecule encodes any protein other than human TRDL-1γ (SEQ ID NO: 2), claim 9 is allowable. Claims 1-8 and 10-17 are not allowed for the reasons set forth above.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
August 24, 2004